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Combating the COVID-19 Crisis: Emerging Issues and Challenges

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Facemasks for prevention of viral respiratory infections in community settings: A systematic review and meta-analysis

Nishant Aggarwal[1], Vignesh Dwarakanathan[2], Nitesh Gautam[1], Animesh Ray[3]

[1]Research Assistant, All India Institute of Medical Sciences, [2]Senior Resident, Department of Community Medicine, All India Institute of Medical Sciences, [3]Assistant Professor, Department of Medicine, All India Institute of Medical Sciences, New Delhi, India

Abstract

Background: There is paucity of evidence on the effectiveness of facemask use in COVID-19 in community settings. **Objectives:** We aimed to estimate the effectiveness of facemask use alone or along with hand hygiene in community settings in reducing the transmission of viral respiratory illness. **Methods:** We searched PubMed and Embase for randomized controlled trials on facemask use in community settings to prevent viral respiratory illnesses published up to April 25, 2020. Two independent reviewers were involved in synthesis of data. Data extraction and risk-of-bias assessment were done in a standard format from the selected studies. Outcome data for clinically diagnosed or self-reported influenza-like illness (ILI) was recorded from individual studies. Pooled effect size was estimated by random-effects model for "facemask only versus control" and "facemask plus hand hygiene versus control." **Results:** Of the 465 studies from PubMed and 437 studies from Embase identified from our search, 9 studies were included in qualitative synthesis and 8 studies in quantitative synthesis. Risk of bias was assessed as low (n = 4), medium (n = 3), or high (n = 1) risk. Interventions included using a triple-layered mask alone or in combination with hand hygiene. Publication bias was not significant. There was no significant reduction in ILI either with facemask alone (n = 5, pooled effect size: −0.17; 95% confidence interval [CI]: −0.43–0.10; P = 0.23; I^2 = 10.9%) or facemask with handwash (n = 6, pooled effect size: (n=6, pooled effect size: −0.09; 95% CI: -0.58 to 0.40; P = 0.71, I^2 = 69.4%). **Conclusion**: Existing data pooled from randomized controlled trials do not reveal a reduction in occurrence of ILI with the use of facemask alone in community settings.

Key words: Coronavirus, COVID-19, hand hygiene, masks, pandemics, severe acute respiratory syndrome coronavirus 2

Introduction

COVID-19, like other respiratory viral illnesses, is thought to spread primarily by droplets, leading to contact of droplets with mucous membranes, either directly or through fomites. While social distancing[1] has been recommended as the most effective means for spreading SARS-CoV-2 infection, wearing a facemask has remained a popular choice in the community. Countries such as Austria, Denmark, South Korea, Singapore, and Japan and a few Indian states/union territories such as Delhi, Uttar Pradesh, Maharashtra, Odisha, and Chandigarh have recommended using facemask in public. The World Health Organization maintains that there is insufficient evidence for the use of medical masks by healthy individuals at home or even in mass gatherings.[2] However, the United States Centers for Disease Control and Prevention (CDC) updated their recommendations in early April to advise the use of a cloth face cover for the general public in settings where social distancing may not be achievable.[3]

Till date, there is no direct evidence on the use of facemasks in preventing transmission of infection in the current COVID-19 pandemic, as suggested by a preprint systematic review.[4] However, different studies including randomized controlled trials (RCTs) have reported (though variably) on the effectiveness of masks with or without other measures (such as hand hygiene) in preventing spread of respiratory viral

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Address for correspondence: Dr. Animesh Ray, Department of Medicine, All India Institute of Medical Sciences, New Delhi, India.
E-mail: doctoranimeshray@gmail.com

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illnesses. The results of such studies may be extrapolated to the current COVID-19 pandemic considering the paucity of evidence.[4] Influenza-like illnesses (ILIs), which are usually a seasonal phenomenon around the globe, are commonly caused by influenza viruses (influenza A, B, and C), adenovirus, respiratory syncytial virus, human rhinovirus, parainfluenza viruses 1–4, and human metapneumovirus (HMPV) along with human coronaviruses.[5-8] We aimed to conduct a systematic review and meta-analysis to estimate the effectiveness of medical mask usage for prevention of ILI in the community settings.

Materials and Methods

This study was conducted according to the preferred reporting items for systematic reviews and meta-analysis guidelines (PRISMA).[9]

Operational definitions

- Facemask: Standard triple-layered medical procedure mask or surgical masks which can be fitted over the face covering the nose and mouth
- Hand hygiene: Intervention consisting of alcohol-based handrub, liquid soap, or alcohol-based gel
- Influenza like-illness: Self-reported or clinically diagnosed fever of 100°F or greater, oral or equivalent, and cough and/or sore throat as defined by the CDC.[10]

Search strategy

On April 25, 2020, we searched the PubMed and Embase databases for articles meeting our inclusion and exclusion criteria without any time limits. The search terms of our study were as follows:

- PubMed – (Community OR general public OR general population OR house*OR slum* OR population based) AND (mask OR facemask OR N95 OR surgical mask OR PPE OR Personal protective equipment) AND (respiratory virus* OR COVID OR COVID-19 OR SARS-CoV-2 OR Influenza OR Flu OR SARS OR MERS OR Ebola OR H1N1). Filters: Case Reports, Classical Article, Clinical Study, Clinical Trial, Controlled Clinical Trial, Journal Article, Multicenter Study, Observational Study, Randomized Controlled Trial
- Embase – (Community OR general public OR general population OR house*OR slum* OR population based) AND (mask OR facemask OR N95 OR surgical mask OR PPE OR Personal protective equipment) AND (respiratory virus* OR COVID OR COVID-19 OR SARS-CoV-2 OR Influenza OR Flu OR SARS OR MERS OR Ebola OR H1N1). Filters: Article, Article in press.

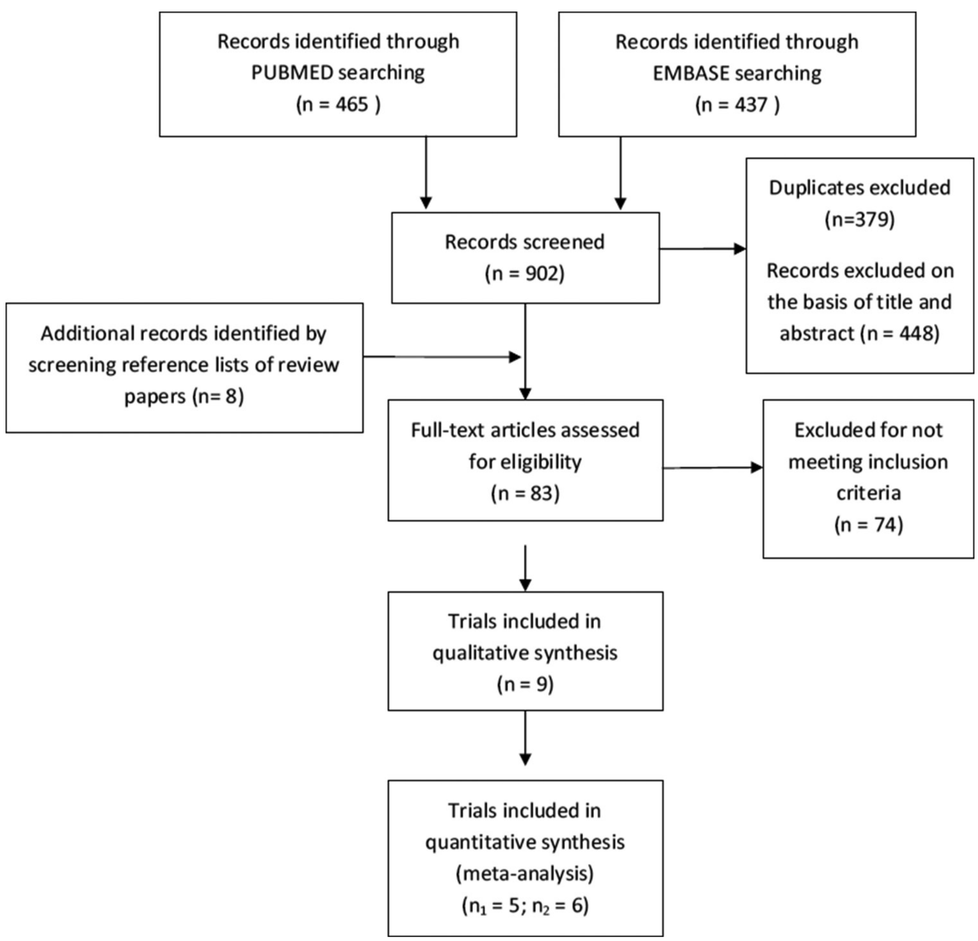

Figure 1: Flow diagram of search strategy and article selection.

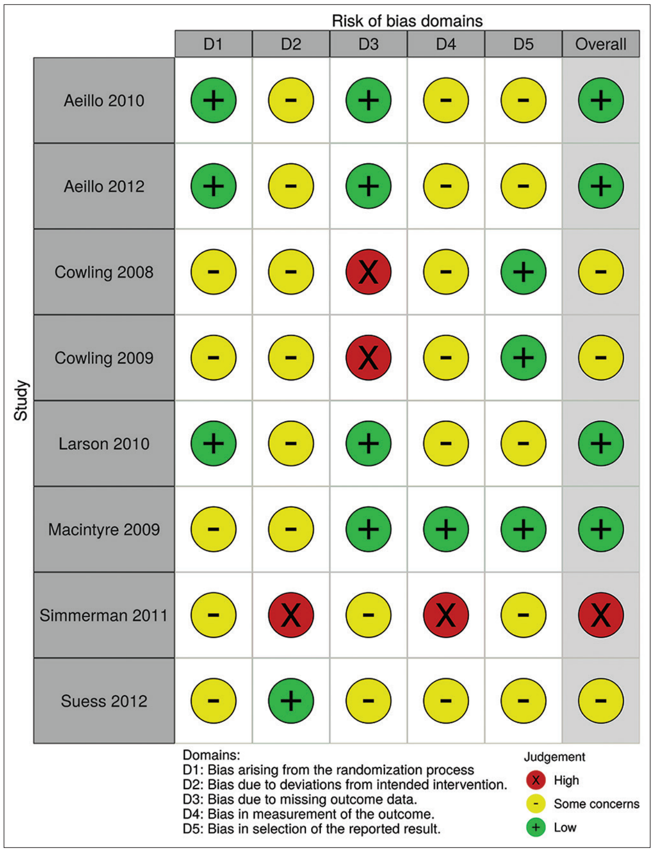

Figure 2: Summary of the risk of bias according to Cochrane risk-of-bias tool.

Review articles were excluded. The reference lists of all relevant articles were screened for identifying additional studies. Our search was limited to articles in English language.

The detailed criteria were as follows:

Inclusion criteria: (1) study type: randomized controlled trials; (2) setting: community; (3) participants: humans with influenza or other viral respiratory illnesses; (4) intervention: the use of facemask with or without other strategies; and (5) outcome: clinically diagnosed influenza or ILIs. Exclusion criteria: (1) trials conducted in the hospital and health-care settings; (2) nonhuman studies; and (3) studies involving mass gatherings, such as Hajj pilgrimage.

Data extraction

The reviewers (NA and VD) independently extracted the data on a predesigned Excel sheet, and any discrepancy was resolved after discussion. The following study and patient characteristics were extracted from each study: sample size of each arm, number of clusters in each arm, intra-cluster correlation coefficient, type of intervention(s), number of events and nonevents among control and intervention groups, given adjusted odds ratio, and 95% confidence interval.

Study selection

The reviewers (NA and VD) independently screened the articles based on the titles and abstracts for potential inclusion in our study. The full-text version of selected articles was reviewed next. If a consensus about inclusion of a particular study could not be reached, the disagreements were resolved with collective discussion. From the studies that were identified, we extracted study type, study settings, sample size, details of intervention and outcome, number of cases and noncases in both arms of the intervention, and odds ratio (if given). Our approach to article selection is outlined in Figure 1.

Risk-of-bias assessment

Risk of bias was assessed by two reviewers (NA and VD) for the method of random sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome reporting (attrition bias), and selective reporting (reporting bias). For each item, risk was either "high", "low" or "unclear". We used the Cochrane risk-of-bias tool (RoB v2.0),[11] along with the additional considerations for cluster-randomized trials wherever it was applicable.[12] Any disagreements were resolved by mutual discussion. A summary of risk of bias is outlined in Figure 2.

Statistical analysis

Data were extracted by NA and VD cross-checked by VD before being entered into the Excel sheet. It was imported to STATA, and the final analysis was done using STATA version 12 (StataCorp, College Station, Texas, USA).[13] Self-reported or clinically diagnosed ILI events were considered as the desired outcome. The sample sizes were adjusted using intra-cluster correlation provided, if the studies were cluster-randomized trial, using general variance inflation method as described in Cochrane handbook.[14] Outcome at the end of period or at 4 weeks was considered. In one study by Larson *et al*.,[15] ILI rate per 1000 person-weeks was reported. Events were calculated for 4 weeks using the provided ILI rate, sample size of each arm, and the assumption that ILI rate would be constant throughout the time period. Odds ratio was the principal summary measure, and wherever the adjusted odds ratio/risk ratio and 95% CI was given, we preferred using them for effect estimate. This was cross-checked by calculating odds ratio with the given number of events and nonevents in intervention and control arm. For meta-analysis, we converted odds ratio into log (odds ratio) and extracted standard error of log (odds ratio).[16] Publication bias was assessed using the Begg's test and visually represented with a funnel plot [Figure 3]. Outcomes were then pooled, and two meta-analyses were done: first, meta-analysis of the use of mask versus control, and second, meta-analysis of the use of mask along with hand hygiene versus control. Heterogeneity was assessed by visual inspection and statistical methods (I square). Random-effects model was planned for calculating the effect size. In sensitivity analysis, we planned to perform the same meta-analysis with fixed-effects model for $I^2 < 25\%$ for "mask and hand hygiene" versus "hand hygiene only" to look into the effectiveness of mask in community setting.

Results

After a search through the PubMed and Embase databases, we identified a total of 902 records. We went through 83 full-text articles, of which 74 were excluded by the inclusion and exclusion criteria [Figure 1]. A systematic review was conducted for 9 cluster RCTs, the results of which are summarized in Table 1.

Of the nine RCTs, six were done in household setting[15,19-24] and two were done with university students as participants in university residence halls.[17,18] Six of these studies compared three arms of intervention – hand hygiene alone, both hand hygiene and facial masks versus no intervention. In all but one RCT,[19] facemasks were used for respiratory protection of contacts of the index case or the individuals still at risk of getting the infection with[15,17,18,20,21,24] or without[22,23] the use of mask by the index case. On the other hand, Canini *et al* (2010) used face masks as source control only for the index case but not the contacts.[19] Therefore, we could not include this study in our meta-analysis. Only one study used N95 in one of their intervention arms.[22] This study compared the efficacy of nonfit P2 masks (similar to N95), surgical masks versus no intervention, and found no significant difference in the rates of ILI among the three arms.[22] Nonfit P2 masks were used because the fit testing was not feasible for the general community in the setting of an ongoing pandemic. There were a few notable findings recorded in the trials. Among the two RCTs conducted by Aiello *et al*. in 2010[17] and 2012,[18] a significant reduction in the weekly ILI rate in the medical masks and hand hygiene arm during week 4–6 and week 3–6 was noted, respectively. Similarly, two trials conducted by Cowling *et al*.[20,21] found a significant difference in the rate of ILI in the hand hygiene and medical mask arm if the interventions were applied within the first 36 h of illness onset in the index case. An RCT conducted by Simmerman *et al*. discovered a significant increase in the odds ratio in the hand hygiene arm and hand hygiene plus facemask arm, suggesting an increased susceptibility to influenza cases with the interventions, which contradicts the perceived protective effect.[23]

No significant publication bias was noted for studies included in mask only versus controls [Figure 3]. We found no significant association between mask use and decrease in events of ILI (pooled effect size: −0.17; 95% confidence

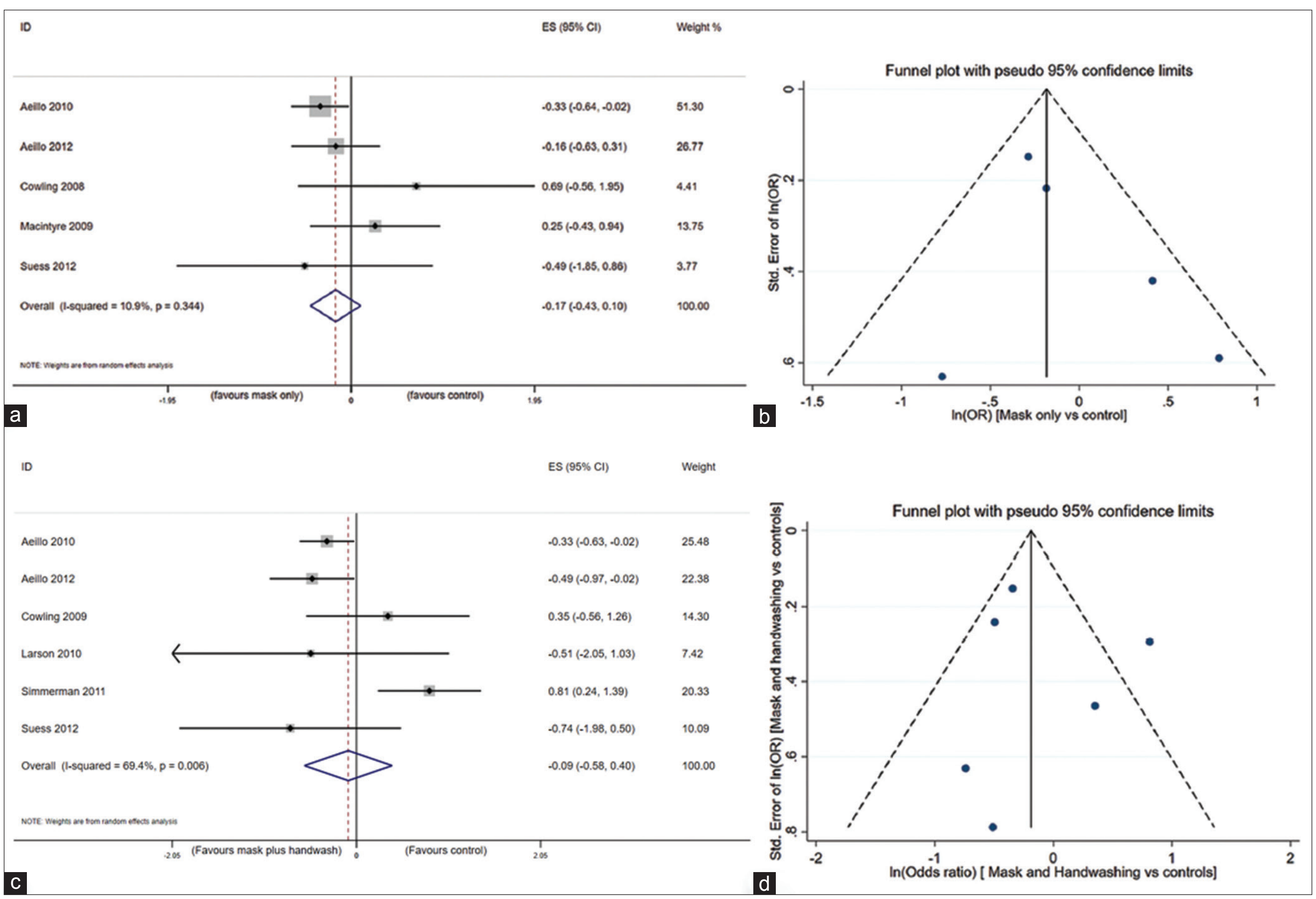

Figure 3: Results of the meta-analysis to determine the effectiveness of: (a) Mask use versus controls (forest plot) ($P = 0.226$). (b) Mask use versus controls (funnel plot) ($P = 0.806$). (c) Masks + hand hygiene versus controls (forest plot) ($P = 0.714$). (d) Masks + hand hygiene versus controls (funnel plot) (P-value $= 0.46$).

Table 1: Summary of studies on mask use in community settings

Author, year of publication, place	Study type, setting, Sample size in final analysis	Intervention groups	Outcome	Results	Conclusion	Limitations, Bias
Aiello *et al*., 2010[17] Michigan, USA During 2006-2007 influenza season	Cluster RCT 7 University residence halls 1150 students	Medical mask (triple-layer mask) Medical mask + hand hygiene (alcohol-based hand sanitizer) Control	Self-reported ILI: Cough + one constitutional symptom (fever, chills, and body aches) Laboratory-confirmed influenza (Culture or RT-PCR)	Mask: 99/347; OR: 0.72 (0.53-0.98) at 4 weeks Mask + hand hygiene: 92/316; OR: 0.65 (0.47-0.91) at 4 weeks Control: 177/487	No significant difference in the cumulative rate of ILI in the three arms Significant reductions in weekly ILI rate in the medical mask + hand hygiene arm during weeks 4-6	Self-reported ILI Not all ILI cases (*n*=368) were laboratory tested (*n*=94) No data on adherence
Aiello *et al*., 2012[18] Michigan, USA During 2007-2008 influenza season	Cluster RCT 37 residence houses in 5 university residence halls 1111 students	Medical mask (triple-layer mask) Medical mask + hand hygiene (alcohol-based hand sanitizer) Control	Self-reported ILI: Cough + one constitutional symptom (fever, chills, and body aches) Laboratory-confirmed influenza (RT-PCR)	Mask: 46/392; OR: 0.85 (0.53-1.36) at 4 weeks Mask + hand hygiene: 31/349; OR: 0.4 (0.2-0.83) at 4 weeks Control: 51/370	No statistically significant reduction cumulative rate of ILI in the three arms Significant reduction in weekly rate of ILI in weeks 3-6 in medical mask + hand hygiene group	Masks only worn inside the residence halls. Transmission may have occurred outside Protective effect may be attributed to handwashing as it was not significant for mask use alone in this study Good compliance: Mask group (5.04 h/day) and mask + hand hygiene group (5.08 h/day)
Canini *et al*., 2010[19] France During 2008-2009 influenza season	Cluster RCT 105 households 306 contacts	Surgical mask for index case only (triple-layer mask) Control	Self-reported ILI: Temperature over 37.8°C with cough or sore throat (primary case definition)	Mask to index case: 24/148; OR: 0.95 (0.44-2.05) Control: 25/158	No significant difference between the ILI rates of two arms	Masks were only used by index case Trial stopped early (intended to include 372 households) No laboratory confirmation of ILI
Cowling *et al*., 2008[20] Hong Kong	Cluster RCT 122 households 350 contacts	Surgical mask (triple-layer mask) Hand hygiene (alcohol-based sanitizer+ liquid soap + alcohol gel) Control	Clinical influenza: Temperature over 37.8°C with cough or sore throat ("Clinical case definition 3") Laboratory-confirmed (culture or RT-PCR) influenza	Mask: 5/61; OR: 2 (0.57-7.02) Hand hygiene only: 3/84; OR: 0.8 (0.22-2.89) Control: 8/205	No significant differences in rate of clinical or laboratory-confirmed influenza in the medical mask versus control arms	Low compliance: 45% in index cases; 21% in contacts Some subjects in the control arm and the hand hygiene arm also used masks
Cowling *et al*., 2009[21] Hong Kong	Cluster RCT 259 households 794 contacts	Hand hygiene (alcohol-based sanitizer+ liquid soap + alcohol gel) Surgical mask (triple-layer mask) + hand hygiene Control	Clinical influenza: Temperature over 37.8°C with cough or sore throat ("Clinical case definition 2") Laboratory-confirmed (RT-PCR) influenza	Hand hygiene: 9/257; OR: 0.81 (0.33-2) Mask + hand hygiene: 18/258; OR: 1.68 (0.68-4.15) Control: 14/279	No significant differences in rate of clinical or laboratory-confirmed influenza in the three arms Significant difference if masks + hand hygiene together applied within 36 h of illness onset in index case	No separate medical mask arm Time lag between symptom onset to intervention and variable adherence may have mitigated intervention effectiveness Some subjects in the control arm and the hand hygiene arm also used masks

Contd...

Table 1: Contd...

Author, year of publication, place	Study type, setting, Sample size in final analysis	Intervention groups	Outcome	Results	Conclusion	Limitations, Bias
Larson *et al*., 2010[15] New York, USA	RCT 509 households 2788 individuals	Hand hygiene (alcohol-based sanitizer) Medical mask (triple-layer mask) + hand hygiene Control	Self-reported URI Self-reported ILI: Temperature over 37.8°C with cough or sore throat Laboratory-confirmed influenza (culture or RT-PCR)	Hand hygiene: 7/946; OR: 1.01 (0.85-1.21) Mask + hand hygiene: 5/938; OR: 0.82 (0.7-0.97) Control: 8/904	No significant difference in rates of URI/ILI/laboratory-confirmed influenza in three arms Significant difference in rate of URI/ILI/Laboratory-confirmed influenza in hand hygiene + medical mask arm	No separate medical mask arm Under-reporting of cases Underpowered Compliance was low for the hand sanitizer and facemask group
MacIntyre 2009[22] Sydney, Australia During 2006-2007 winter season	Cluster RCT 143 households 286 contacts	Surgical masks (triple-layer mask) Nonfit P2 masks (similar to N95) Controls	Self-reported ILI: Fever with ≥2 of sore throat, cough, sneezing, runny nose, nasal congestion, and headache. Laboratory-confirmed respiratory viral infection	Surgical mask: 21/94; OR: 1.29 (0.69-2.31) P2 mask: 14/92; OR: 0.95 (0.49-1.84) Control: 16/100	No significant difference in ILI and laboratory-confirmed respiratory viral detection in the three arms	Self-reported ILI 21% in mask use groups were adherent Fit testing for P2 masks not conducted
Simmerman *et al*., 2011[23] Bangkok Thailand	Cluster RCT 348 households 885 contacts	Hand hygiene (liquid soap) Surgical mask + hand hygiene Control	Self-reported ILI: Fever with cough or sore throat Laboratory-confirmed influenza by RT-PCR and serological testing	Hand hygiene: 50/292; OR: 2.09 (1.25-3.5) Mask + hand hygiene: 51/291; OR: 2.15 (1.27-3.62) Control: 26/302	No significant difference between the odds ratios for secondary influenza infection in the three arms. Significant increase in odds ratio for handwashing and handwashing + mask arm (opposite to hypothesized protective effect.)	Exposure may have occurred outside house Poor adherence to interventions Introduction of national hygiene campaign due to 2009 H1N1 pandemic which caused substantial increase in hand hygiene and mask use among the control arm (index cases: 4%-52%; families: 17.6%-67.7%) Sensitization bias: Subjects in intervention arm may have been more likely to report perceived symptoms than the control arm
Suess *et al*., 2012[24] Berlin, Germany During 2009-2010 pandemic and 2010-2011 influenza season	Cluster RCT 84 households 218 contacts	Surgical mask (triple-layer mask) Surgical mask + hand hygiene (alcohol-based rub) Control	Self-reported ILI: Fever with cough or sore throat Laboratory-confirmed influenza (RT-PCR)	Mask: 6/69; OR: 0.61 (0.2-1.87) Mask + hand hygiene: 6/67; OR: 0.5 (0.16-1.58) Control: 14/82	No significant difference in rates of ILI or RT-PCR-confirmed influenza between the three arms	Cannot tell role of intensified hand hygiene Laboratory testing of the contacts was only done for the virus subtype of index case About 50% were adherent to mask use

RT-PCR: Reverse transcription-polymerase chain reaction, ILI: Influenza-like illness, OR: Odds ratio, URI: Upper Respiratory Illness

interval [CI]: −0.43–0.10; $P = 0.23$). Heterogeneity was low by I^2 statistics ($I^2 = 10.9\%$).

Pooled effect of the usage of mask and hand hygiene against controls was calculated [Figure 3]. Publication bias was not

significant for studies included in mask and hand hygiene versus controls (P value by Begg's test = 0.45). There was no significant decrease in ILI events with mask and hand hygiene compared to controls (pooled effect size: −0.09; 95% CI: -0.58 to 0.40; $P = 0.71$, $I^2 = 69.4\%$).

Sensitivity analysis

We conducted the following sensitivity analyses [Figure 4]:

1. Using fixed-effects model for mask only versus control: Effect size remained insignificant even after using fixed-effects model ($n = 5$, pooled effect size: −0.19; 95% CI: −0.424–0.043; $P = 0.11$, $I^2 = 10.9\%$)
2. Using random-effects model for mask and hand hygiene versus control after excluding study by Simmerman *et al*.:[23] This study was excluded for the following reasons. Of the six studies used, effect size of a study by Simmerman *et al*. was outside the funnel. Furthermore, Simmerman *et al*. noted that the adherence to intervention was particularly poor and the social customs in Bangkok lead to low use of mask. In addition, due to H1N1 outbreak, mask use and hand hygiene in the control group substantially increased.[23] The meta-analysis conducted after excluding this study showed that mask plus hand hygiene was associated with lower events of ILI ($n = 5$, pooled effect size: −0.344; 95% CI: -0.583 to -0.105; $P = 0.005$, $I^2 = 0\%$)
3. Random-effects model between mask and hand hygiene (intervention group) versus mask only (control): Effect size was insignificant between both the interventions for preventing events of ILI ($n = 3$, pooled effect size: −0.136; 95% CI: −0.406–0.133; $P = 0.321$, $I^2 = 0\%$)
4. Random-effects model between mask and hand hygiene (intervention) versus hand hygiene only (control): No significant difference was found in ILI events ($n = 3$, pooled effect size: 0.102; 95% CI: −0.485–0.689; $P = 0.73$, $I^2 = 0\%$).

Discussion

The pooled estimate of the randomized control trials did not show any significant reduction of ILI by the use of facemasks with or without hand hygiene in community settings. However, sensitivity analysis showed a significant protective role of facemasks and hand hygiene after the study by Simmerman *et al.* was excluded[23] due to the high risk of bias and probable contamination. Thus, the use of facemasks along with proper hand hygiene methods, but not facemasks alone, showed statistically significant benefits vis-à-vis no interventions. It may be reasoned that addressing fomite-borne transmission in addition to prevention of droplet infections by masks is important to derive protective benefits, if any. However, in a pandemic situation, the exact degree of protection offered by facemask use, over and above other practices such as hand hygiene, still remains obscure.

Two main factors, namely correct fitting of facemask and adherence to facemask usage, are important in preventing droplet infections. Adherence to facemask use was low in the intervention groups in all the studies which reported it [Table 1]. Correct fit of facemask was not reported in any

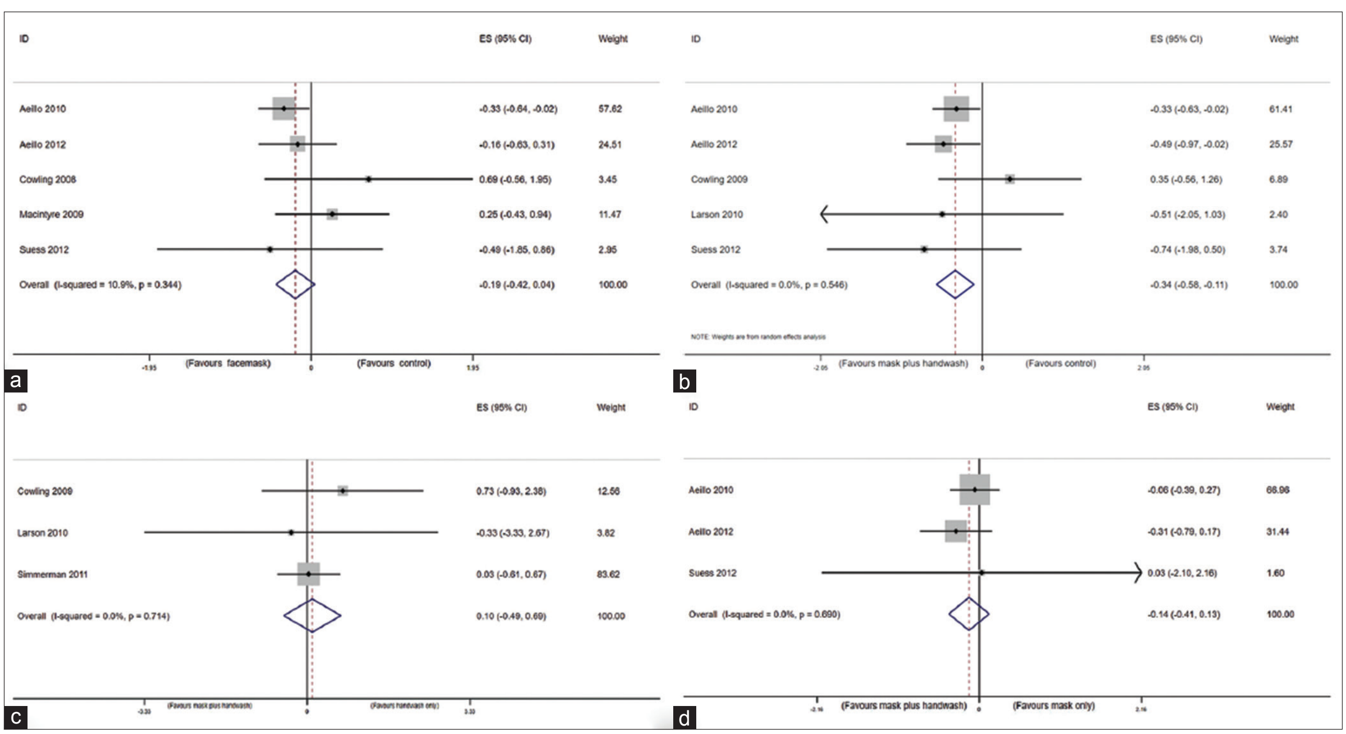

Figure 4: Sensitivity analysis results of the meta-analyses to determine the effectiveness of: (a) Masks versus controls using fixed-effects model. (b) Masks + hand hygiene versus controls excluding the Simmerman *et al.* study (P value = 0.005). (c) Masks + hand hygiene versus hand hygiene only. (d) Masks + hand hygiene versus mask use only.

of the studies included in this meta-analysis. These may be representative of the real-life scenario where both long-term adherence and proper usage of facemasks are considered to be major hurdles for widespread implementation and derived benefits. In addition, the use of medical mask may provide a false sense of security and may lead to neglect of other essential practices such as social distancing and hand hygiene, while also diverting mask supply away from the health-care workers.[2]

Our study had a few limitations. Only a small number of studies were found eligible in our meta-analyses. For calculation of pooled estimate for mask use against control, larger weightage was given to one study.[18] In addition, it may be assumed that certain practices such as hand hygiene may already be in practice by all arms in the studies, which would lead to regression toward null value. Furthermore, in the studies in which facemask was used by the index case and contacts, there could have been a time lag between infection inoculation and start of intervention. Subjects of the study could have also acquired infection outside the study area, which may not have been accounted in the individual studies. Another limitation of our study was the nonuniformity in the definition of ILI among the studies. Most of our included studies[15,20,21,23,24] used the standard CDC case definition of ILI as one of the outcomes, but some studies[17,18,22] used a different definition as described in Table 1.

Thus, using facemask alone may not be an effective strategy in preventing transmission of viral respiratory diseases in community settings. Existing data pooled from the RCTs do not reveal a reduction in the incidence of ILI with the use of facemask alone in community settings. Well-conducted clinical studies are warranted to determine whether these results can be applied to the COVID-19 pandemic.

Conclusion

Available evidence does not confirm a protective effect of face mask usage alone in a community setting against influenza-like illnesses (and potentially, the COVID-19). For maximum benefit, mask use should be combined with other essential non-pharmaceutical interventions like hand hygiene.

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Conflicts of interest

There are no conflicts of interest.

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